

Application Serial No. 10/806,260
Response dated June 12, 2007
Reply to Final Office Action dated February 15, 2007

In the claims:

1. (Previously Presented) A process for preparing gabapentin tannate to be used in pharmaceutical composition for treating a condition of the central nervous system in a mammalian subject, comprising: reacting gabapentin with tannic acid to produce a pharmaceutically effective amount of gabapentin tannate.
2. (original) The process of claim 1 including selecting said tannic acid from either natural or synthetic origin.
3. (original) The process of claim 1 including providing one or more pharmaceutically acceptable excipients.
4. (original) The process of claim 1 including providing said pharmaceutically effective amount of gabapentin tannate in liquid or semi-solid dosage forms.
5. (original) The process of claim 1 including providing said pharmaceutically effective amount of gabapentin tannate in suspension dosage form.
6. (Previously Presented) A process for preparing gabapentin tannate to be used in a pharmaceutical composition for treating a condition of the central nervous system in a mammalian subject, comprising:
mixing tannic acid and a dispersing agent in a solvent to obtain a dispersion; and
adding gabapentin to said dispersion.

7. (original) The process of claim 6 including dissolving said gabapentin in a solvent before adding said gabapentin to said dispersion.
8. (original) The process of claim 6, including providing said dispersing agent in an amount equal to between about 0.05 to about 5.0% by weight of said dispersion.
9. (original) The process of claim 6, including providing said tannic acid in an amount equal to between about 0.05 to about 50.0% by weight of said dispersion.
10. (original) The process of claim 6, including providing said dispersing agent and said tannic acid in said composition at a weight ratio of between about 0.1:2 to about 100:1.
11. (original) The process of claim 6, including providing said gabapentin and said tannic acid in said composition at a weight ratio of between about 0.1:1 to about 100:1.
12. (original) The process of claim 6, including selecting said solvent from a group of solvents consisting of water, purified water, isopropyl alcohol, ethanol, glycerin, propylene glycol, mineral oil and mixtures thereof.
13. (original) The process of claim 6, further including adding one or more pharmaceutically acceptable excipients to said composition and selecting said dispersing agent and said excipients from a group consisting of magnesium aluminum silicate, xanthan gum, cellulose compounds, acacia, tragacanth, kaolin, pectin and mixtures thereof.
14. (original) The process of claim 6, further including adding one or more sweetening agents to said composition, and selecting said sweetening agents from a group consisting of sucrose, saccharin sodium, aspartame, sucralose and mixtures thereof.
15. (original) The process of claim 14, including providing said sweetening agent in an amount equal to between about 5.0 to about 50.0% by weight of said composition.

16. (original) The process of claim 6, including adding one or more preservatives to said composition and selecting said preservatives from a group consisting of methylparaben, propylparaben, butylparaben and mixtures thereof.

17. (original) The process of claim 16, including providing said preservative in an amount equal to between about 0.05 to about 2.0% by weight of said composition.

18. (original) The process of claim 6, including maintaining a pH of between about 2.0 to about 11.0 during said process.

19. (original) The process of claim 6, including adding one or more excipients to said composition and selecting said excipients from a group consisting of a thickening agent, a suspending agent, a sweetening agent, a flavoring agent, a preserving agent, a buffering agent, an anti-caking agent and mixtures thereof.

20. (Previously Presented) A gabapentin tannate composition for treating a condition of the central nervous system in a mammalian subject, comprising as an active ingredient a pharmaceutically effective amount of gabapentin tannate.

21. (original) The composition of claim 20 further including one or more pharmaceutical excipients.

22. (original) The composition of claim 21, wherein said excipients are selected from a group consisting of a dispersing agent, an anti-clumping agent, a thickening agent, a suspending agent, a sweetening agent, a flavoring agent, a preserving agent, a buffering agent, an anti-caking agent, a solvent and any mixtures thereof.

23. (original) The composition of claim 21, wherein said composition further includes one or more solvents selected from a group consisting of water, purified water, ethanol, isopropyl alcohol, glycerin, propylene glycol, mineral oil and mixtures thereof.
24. (original) The composition of claim 21, wherein said composition further includes one or more anti-caking agents selected from a group consisting of magnesium aluminum silicate, xanthan gum, cellulose compounds, acacia, tragacanth, kaolin, pectin and mixtures thereof.
25. (original) The composition of claim 21, wherein said composition further includes one or more sweetening agents selected from a group consisting of sucrose, saccharin sodium, aspartame, sucralose and mixtures thereof.
26. (original) The composition of claim 21, wherein said composition further includes one or more preserving agents selected from a group consisting of methylparaben, propylparaben, butylparaben and mixtures thereof.
27. (original) The composition of claim 21, wherein said composition further includes one or more anti-clumping agents selected from a group consisting of magnesium aluminum silicate, xanthan gum, polyvinylpyrrolidone, cellulose compounds, magnesium stearate, colloidal silica, talc, stearic acid, calcium stearate, lactose, mannitol, sucrose and mixtures thereof.
28. (original) The composition of claim 20, wherein said composition is in a liquid or semi-solid dosage form.
29. (original) The composition of claim 20, wherein said composition is in suspension form.
30. (withdrawn) A method of treating a condition of the central nervous system in a mammalian subject, comprising: administering a pharmaceutically effective amount of gabapentin tannate wherein the tannic acid component is of either natural or synthetic origin.

31. (withdrawn) The method of claim 30 wherein said administering step is performed orally.

32. (withdrawn) The method of claim 30, including providing between about 0.1 to about 3600 mg of gabapentin in gabapentin tannate salt form.

33. (new) A process for preparing gabapentin tannate to be used in a pharmaceutical composition for treating a condition of the central nervous system in a mammalian subject, comprising:

- (i) reacting gabapentin with tannic acid to produce gabapentin tannate; and
- (ii) directly incorporating the gabapentin tannate into a suitable pharmaceutical suspension dosage form without further purification and isolation to yield a dosage form having a therapeutically effective amount of gabapentin tannate.